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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,437	10/15/2001	Jeffrey A. Heroux	2528-8	3932

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,437

Applicant(s)

HEROUX ET AL

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-67, 69, 77-87 and 89 is/are pending in the application.
- 4a) Of the above claim(s) 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-67, 69, 81-87 and 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on June 20, 2006 has been entered.

Status of the Application

2. Currently claims 45-67, 69, 81-87, 89 are pending. Claims 45-46, 50-51, 55-56, 60, 64 are amended. Claims 1-44, 68, 70-76 and 88 are cancelled. Claims 77-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment. All amendments and arguments have been thoroughly reviewed and deemed persuasive in view of amendment. The instant amendment introduces new limitations in the independent claims 45-46, 50, 55-56, 60, that is, "wherein the presence, concentration, or activity of said enzyme or said factor is not known" which are not present in the previously examined claims. The amendment introduced new limitations as shown above and changed the scope of the independent claims to overcome the rejection under 103(a). Now the scope of the independent claims is changed, accordingly the previous rejections are withdrawn and the following new combination of rejections has been applied to reject newly presented claims. This action is made Final, necessitated by Amendment.

New Grounds of Rejections necessitated by amendment

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 45-67, 69, 81-87, 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shukla et al. (Nucleic Acids Res., Vol. 22, No. 9, pp. 1626-1631, 1994) in view of Massey et al. (USPN. 5,866,434).

Shukla et al. teach a method of claims 45-46, 50, 55, 56, 60, for assaying a sample (cell-free extracts) for enzyme activity (DNA helicases / nuclease) that modifies the rate of joining a first substrate (activity gel substrate with partially duplex M13mp18 chromosomes radiolabeled) with a second substrate (helicase activity gels with partially double-stranded M13 circular DNA) to form a product (displaced DNA product) comprising

(a) forming a composition comprising said sample (cell-free extract) said first and second first and second substrates (see page 1627, col. 2, paragraphs 1-2)

(b) incubating said composition under conditions that form said product in the presence of said enzyme, wherein said enzyme activity is not a part of the product (see page 1627, col. 2, paragraph 1 under visualization of blotted products, page 1628, paragraph 1 under results and discussion),

(e) measuring the presence of the product as an indication of said enzyme activity in said sample (see page 1627, col. 2, paragraph 1 under visualization of blotted products indicating lightning plus intensifying screen, page 1628, paragraph 1 under results and discussion),

With regard to claim 51, Shukla et al. teach that said enzyme catalyzes formation of covalent bond between said first and second substrate (see page 1628, paragraph 1 under results and discussion)

With regard to claim 53, 63, Shukla et al. teach that said first and second substrates comprise nucleic acids (see page 1627, col. 1, paragraph 1 and 2),

With regard to claim 54, Shukla et al. teach that the enzyme is a nucleic acid helicase (see page 1628, paragraph 1 under results and discussion)

With regard to claims 55-56, 60-61, 64, Shukla et al. teach that said enzyme has a nuclease activity (see page 1628, col. 2, paragraph 2),

With regard to claim 87, Shukla et al. teach that said factor is ATP (see page 1628, Fig.2)

However, Shukla et al. did not teach measuring said enzyme activity using a luminescent label immobilized on an electrode and measuring the emitted luminescence as an indication of said enzyme activity.

Massey et al. teach a method of claims 45-46, 50, of assaying a sample for an activity that modifies the rate of joining that joins (binds) a first substrate (an assay-performance substance) and a second substrate (a functionalized graphic nanotube) to form a product (binding complex) comprising:

(a) forming a composition comprising said sample, said first and second substrate (see col. 13, line 9-19, line 31-43);

- (b) incubating said composition to form said product (see col. 13, line 20-22, line 44-45);
- (c) immobilizing a luminescent label linked to said product on an electrode (see col. 13, line 15-22, line 31-45);
- (d) applying a voltage at said electrode to induce luminescent label to emit luminescence (see col. 13, lines 24-27, line 48-51);
- (e) measuring emitted luminescence to measure said activity (see col. 13, line 29-31, line 52-54).

With regard to claim 46-47, 85, Massey et al. teach that said first substrate is linked to a luminescent label (see col. 13, line 15-17) and said second substrate linked (attached) to electrode (magnetically responsive nanotubes) (see col. 13, line 18-19);

With regard to claim 47, 50, 81-82, Massey et al. teach that the second substrate is linked (attached) to said electrode via avidin (capture moiety) biotin linkage (see col. 40, line 41-50);

With regard to claims 48-49, Massey et al. teach that said electrode (nanotube fibrils) linked to one or more additional substrates forming a patterned array of substrates comprising at least two substrates that differ in structure (see col. 52, line 27-67, col. 53, line 1-2, wherein nanotube fibril comprises biotinylated fibril and alkylated biotinylated fibrils having two different structures);

With regard to claims 52-53, Massey et al. teach that said first substrate comprises peptides and nucleic acids (see col. 16, line 45-64);

With regard to claim 67, Massey et al. teach said electrode comprises conductive particles with in or on a polymeric material (see col. 11, line 47-67, col. 12, lines 1-28);

With regard to claims 54, 68, 87, Massey et al. teach that said activity is an enzyme activity comprising catalytic enzymes as glucosidases, dehydrogenases (see col. 47, line 10-15, col. 49, line 55-67, col. 50, line 1-67);

With regard to claim 65-66, 89, Massey et al. teach that said electrode comprises elemental carbon in the form of graphite (see col. 13, line 18-19).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of assaying enzyme activity as taught by Shukla et al. with a step of luminescent label on an electrode as taught by Massey et al. for the purpose of enhancing the efficiency of detecting the enzyme activity in said sample. One skilled in the art would be motivated to combine the method as taught by Shukla et al. with the chemiluminescent label detection as taught by Massey et al. because Massey et al. explicitly taught that the use of luminescence assays using particles having high surface area for immobilization of assay performance substances to achieve advantageously high light emission (see col. 6, line 24-27). The ordinary artisan would have a reasonable expectation of success that inclusion of said luminescence assay system to detect said enzyme activity taught by Shukla et al. would result in increase in the sensitivity of detection of said enzyme and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Response to arguments:

4. With regard to the informalities, Applicants' response is fully considered. Examiner made a suggestion, it is not mandatory if the Applicants intend not change the recitation of alternate claim language.

5. With regard to claim interpretation, Applicants' arguments are fully considered and Examiner has interpreted DNA polymerase activity as enzyme activity for examination purposes. And the instant claims are not limited to said enzyme.

6. With regard to the rejection of claim 51 under 35 USC 112, second paragraph, Applicants' amendment and arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment.

7. With regard to the rejection under 35 USC 103(a) as being unpatentable over Comb in view of Massey et al., Applicants' amendment and arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and new grounds of rejections.

8. With regard to the rejection under 35 USC 103(a) as being unpatentable over Sivaraja in view of Massey et al., Applicants' amendment and arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment and new grounds of rejections.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Suryaprabha Chunduru
SURYAPRABHA CHUNDURU
PATENT EXAMINER
9/12/06